

REMARKS

Claims 1-35 were originally pending in the application. Claims 24-25 and 30-35 have been canceled in response to a restriction requirement. Claims 1-23, 26-29 are currently pending in the application. Claims 1 and 28 have been amended. Claims 1-29, 36 and 37 have been rejected. The Applicants do not believe that claims 36-37 are currently pending in this application. Clarification from the Examiner is requested. Reexamination and reconsideration of the claims are respectfully requested.

Rejection of Claims 1-4, 8-9, and 11-12, 14-16, 18-25, and 27-28 Under 35 U.S.C. §102(b), Should be Withdrawn

Claims 1-4, 8-9, and 11-12, 14-16, 18-25, and 27-28 were rejected under 35 U.S.C. §102(b) as being anticipated by USP 5,225,326 to Bresser et al. The Examiner states that Bresser teaches a one-step in situ hybridization assay for detecting multiple biopolymers in the same cell.

Claims 1 and 28 have been amended to recite assay methods comprising providing a sensor that can bind to the target in an alcoholic preservative solution that does not contain formamide. Since the method taught in Bresser specifically teaches the use of formamide during the binding of the sensor to the target, Bresser cannot anticipate amended Claims 1 and 28. Therefore, Applicants request that the rejection of Claims 1 and 28 under 35 U.S.C. §102(b) as well as those claims which depend from Claims 1 and 28 be withdrawn.

Rejection of Claim 28 Under 35 U.S.C. §102(e), Should be Withdrawn

Claim 28 was rejected under 35 U.S.C. §102(e) as being anticipated by USP 6,969,585 to Lorincz et al. The Examiner states that Lorincz teaches a universal collection medium for cell collection which allows for cytology and direct molecular analysis on cells preserved in a single sample. The Applicants respectfully disagree. The Examiner states that Lorincz teaches a method for identifying a sensor which specifically binds to a desired target comprising contacting a sample suspected of containing a target of interest with a detectable sensor, wherein said contacting takes place in a preservative solution comprising an amount of one or more water-soluble alcohols effective to preserve such solution against at least one contaminant. As support for this statement, the Examiner points to Example 1 of Lorincz as teaching the addition of DNA biotinylated probes added directly to samples and incubated for 65°C for hybridization. The Applicants respectfully disagree. Example 1 of Lorincz states that the assay for nucleic acids follows "...in general principle the method for detecting HIV RNA by the Digene Hybrid Capture HIV Test, described in WO 93/10263" (see column 10, last paragraph). The method taught in WO 93/10263 is exemplified by Example 1 of the application. In Example 1, the method clearly requires that "...after hydrolysis, a 150ul aliquot was removed from the sample tube and added to 50ul of a probe diluent containing Probe A, B, or C." (emphasis added) (see page 26, lines 29-31). Thus, the contacting of a target of interest with a detectable sensor does not take place in Lorincz in a preservative solution as specified by the current claims. Since the method taught in Lorincz specifically teaches the binding of the sensor to the target in a completely different solution than the cell preservative solution, Lorincz cannot anticipate Claim 28. Therefore, Applicants request that the rejection of Claim 28 under 35 U.S.C. §102(e) be

withdrawn.

For all the reason stated above, the Applicant respectfully requests that all rejections of claims under 35 U.S.C. §102 be withdrawn.

Rejection of Claims 1-4, 14-16, 18-19, and 23-27 Under 35 U.S.C. §103(a), Should be Withdrawn

Claims 1-4, 14-16, 18-19, and 23-27 were rejected under 35 U.S.C. §103(a) as being unpatentable over USP 6,969,585 to Lorincz et al. as applies to claim 28 and in further view of USP 6,165,723 to Shah et al. The Applicants traverse this rejection.

For the reasons stated above, Lorincz does not anticipate the method of the present invention because the contacting of a target of interest with a detectable sensor does not take place in Lorincz in a preservative solution as specified by the current claims. Since the method taught in Lorincz specifically teaches the binding of the sensor to the target in a completely different solution than the cell preservative solution, Lorincz cannot anticipate Claim 1. Therefore, Applicants request that the rejection of Claim 1 under 35 U.S.C. §102(e) and all claims which depend from Claim 1 (2-4, 14-16, 18-19, and 23-27) be withdrawn.

Rejection of Claims 5, 7, 29, and 36-37 Under 35 U.S.C. §103(a), Should be Withdrawn

Claims 5, 7, 29, and 36-37 were rejected under 35 U.S.C. §103(a) as being unpatentable over USP 5,225,326 to Bresser et al. as applies to claims 1-4, 8-9, 11-12, 14-16, 18-25, and 27-28, and in further view of USP 6,280,946 to Hyldig-Nielsen et al.

Claims 1 and 28 have been amended to recite assay methods comprising providing a

sensor that can bind to the target in an alcoholic preservative solution that does not contain formamide. Since the method taught in Bresser specifically teaches the use of formamide during the binding of the sensor to the target, Bresser cannot anticipate amended Claims 1 and 28. Therefore, Applicants request that the rejection of Claims 5, 7, 29, which depend from Claims 1 and 28, under 35 U.S.C. §103(a) be withdrawn.

As mentioned previously, the Applicants do not believe that claims 36-37 are currently pending in this application. Thus, the Applicant request that the rejection of claims 36-37 be withdrawn.

Rejection of Claim 6 Under 35 U.S.C. §103(a), Should be Withdrawn

Claim 6 was rejected under 35 U.S.C. §103(a) as being unpatentable over USP 5,225,326 to Bresser et al. as applies to claims 1-4, 8-9, 11-12, 14-16, 18-25, and 27-28, and in further view of Kumar et al. (Bioorganic & Medicinal Chemistry, 1998, vol. 8, pp.2219-2222).

Claim 1 has been amended to recite assay methods comprising providing a sensor that can bind to the target in an alcoholic preservative solution that does not contain formamide. Since the method taught in Bresser specifically teaches the use of formamide during the binding of the sensor to the target, Bresser cannot anticipate amended Claim 1. Therefore, Applicants request that the rejection of Claim 6 which depends from Claim 1, under 35 U.S.C. §103(a) be withdrawn.

Rejection of Claim 10 Under 35 U.S.C. §103(a), Should be Withdrawn

Claim 10 was rejected under 35 U.S.C. §103(a) as being unpatentable over USP 5,225,326 to Bresser et al. as applies to claims 1-4, 8-9, 11-12, 14-16, 18-25, and 27-28, and in further view of Bruchez et al. (Science, 1998, vol. 281, pp.2013-2016).

Claim 1 has been amended to recite assay methods comprising providing a sensor that can bind to the target in an alcoholic preservative solution that does not contain formamide. Since the method taught in Bresser specifically teaches the use of formamide during the binding of the sensor to the target, Bresser cannot anticipate amended Claim 1. Therefore, Applicants request that the rejection of Claim 10 which depends from Claim 1, under 35 U.S.C. §103(a) be withdrawn.

Rejection of Claim 13 Under 35 U.S.C. §103(a), Should be Withdrawn

Claim 13 was rejected under 35 U.S.C. §103(a) as being unpatentable over USP 5,225,326 to Bresser et al. as applies to claims 1-4, 8-9, 11-12, 14-16, 18-25, and 27-28, and in further view of USP 5,256,535 to Ylikoski et al.

Claim 1 has been amended to recite assay methods comprising providing a sensor that can bind to the target in an alcoholic preservative solution that does not contain formamide. Since the method taught in Bresser specifically teaches the use of formamide during the binding of the sensor to the target, Bresser cannot anticipate amended Claim 1. Therefore, Applicants request that the rejection of Claim 13 which depends from Claim 1, under 35 U.S.C. §103(a) be withdrawn.

Rejection of Claim 17 Under 35 U.S.C. §103(a), Should be Withdrawn

Claim 6 was rejected under 35 U.S.C. §103(a) as being unpatentable over USP 5,225,326 to Bresser et al. as applies to claims 1-4, 8-9, 11-12, 14-16, 18-25, and 27-28, and in further view of Fukasawa et al. (Science, 1996, vol. 271, pp.1744-1747).

Claim 1 has been amended to recite assay methods comprising providing a sensor that can bind to the target in an alcoholic preservative solution that does not contain formamide.

Since the method taught in Bresser specifically teaches the use of formamide during the binding of the sensor to the target, Bresser cannot anticipate amended Claim 1. Therefore, Applicants request that the rejection of Claim 17 which depends from Claim 1, under 35 U.S.C. §103(a) be withdrawn.

For all the reason stated above, the Applicant respectfully requests that all rejections of claims under 35 U.S.C. §103(a) be withdrawn.

CONCLUSION

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 502855 referencing attorney docket number 12.033011.

Customer No, 0000 38732

Respectfully submitted,



Theodore R. Allen
Registration No. 41,578
Cytac Corporation
250 Campus Drive,
Marlborough, MA 01752
Tel: 508-263-8490
Fax: 508-263-2959